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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**VIVUS, INC. and
MITSUBISHI TANABE PHARMA
CORPORATION,**

Plaintiffs,

v.

**HETERO USA, INC., HETERO LABS
LIMITED UNIT-III, and HETERO
LABS LIMITED,**

Defendants.

Civil Action No. 16-4560 (KSH)(CLW)

(Filed Electronically)

STIPULATION AND ORDER OF DISMISSAL

The Court, upon the consent and request of Plaintiffs Vivus, Inc. ("Vivus") and Mitsubishi Tanabe Pharma Corp. ("Mitsubishi," and together with Vivus, "Plaintiffs") and Hetero USA, Inc. ("Hetero USA"), Hetero Labs Limited Unit III ("Hetero Unit III"), and Hetero Labs Limited ("Hetero Labs", and together with Hetero USA and Hetero Unit III, "Hetero" or "Defendants") (collectively, the "Parties"), hereby enters into the record the following Stipulated Facts and issues the following Order of Dismissal:

STIPULATED FACTS

1. This Court has subject matter jurisdiction over this patent infringement action (the “Action”). The Court has personal jurisdiction over Plaintiffs and Defendants and venue is proper in this Court.

2. In this Action, Plaintiffs have charged Defendants with infringement of certain claims of United States Patent Nos. 9,656,935 and 7,501,409 (“the Asserted Patents”) in connection with Defendants’ submission of Abbreviated New Drug Application (“ANDA”) No. 209266, directed to a generic avanafil tablet product for the treatment of erectile dysfunction (hereinafter, the “Generic Product”), to the U.S. Food and Drug Administration (“FDA”).

3. ~~Defendants have not, at this time, rebutted the statutory presumption that the~~
Asserted Patents are valid and enforceable in this Action.

4. For purposes of settlement, Defendants admit that the submission of ANDA No. 209266 to the FDA for the purpose of obtaining regulatory approval to engage in the commercial manufacture, use and/or sale of the Generic Product within the United States prior to the expiration of the Asserted Patents was a technical act of patent infringement with respect to one or more claims of each of the Asserted Patents.

STIPULATED ORDER OF DISMISSAL

Accordingly, pursuant to the above Stipulated Facts, and upon the consent and request of Plaintiffs and Defendants, **IT IS HEREBY ORDERED, ADJUDGED AND DECREED THAT:**

1. The filing of ANDA No. 209266 was a technical act of infringement of each of the Asserted Patents under 35 U.S.C. § 271(e)(2)(A). No decision of the Court has been obtained by either party regarding the presumptive validity or enforceability of United States

Patent Nos. 6,656,935 and 7,501,409 and/or whether the product described by ANDA No. 209266 infringes those patents.

2. All other claims, defenses, and counterclaims in this Action are hereby dismissed, without prejudice.

3. Defendants, their officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, are hereby enjoined from manufacturing, using, offering to sell or selling within the United States, or importing into the United States, the Generic Product during the life of the Asserted Patents, including any extensions and pediatric exclusivities, without a license or other authorization by Plaintiffs.

4. This Court retains jurisdiction over Plaintiffs and Defendants solely for purposes of enforcing this Stipulation and Order Of Dismissal.

5. Each party shall bear its own fees and costs in connection with this Action, including attorney fees.

6. The Clerk of the Court is directed to enter this final judgment forthwith.

7. Nothing herein shall prohibit or restrict Defendants from maintaining their Paragraph IV certifications in ANDA No. 209266 under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (as amended or supplemented).

Dated: January 5, 2017

By: s/ Charles M. Lizza

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SO ORDERED this 5th day of January, 2017



Hon. Katharine S. Hayden, U.S.D.J.